contain. The pH of the solution containing 1,600 micrograms of penicillin G per milliliter is not less than 5.0 and not more than 7.5. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1) (i), (v) and (vi) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 2.5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit (0.600 microgram) of penicillin G per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 1,600 micrograms of penicillin G per milliliter.

### § 460.146 Tetracycline concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tetracycline concentrated stock solutions for use in preparing antimicrobial susceptibility test panels are frozen aqueous tetracycline hydrochloride stock solutions serially diluted with distilled water to contain approximately the following concentrations: 640, 320, 160, 80, 40, 20, and 10 micrograms of tetracycline per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of tetracycline that it is represented to contain. The pH of the solution containing 640 micrograms of tetracycline per milliliter is not less than 3.0 and not more than 7.0. The tetracycline hydrochloride used conforms to the standards prescribed by § 446.81a(a)(1) (i), (vi), (vii), and (viii) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with distilled water to the reference concentration of 0.24 microgram of tetracycline per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 640 micrograms of tetracycline per milliliter.

### § 460.149 Tobramycin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tobramycin concentrated stock solutions for use in preparing antimicrobial susceptibility test panels are frozen aqueous tobramycin sulfate stock solutions serially diluted with distilled water to contain approximately the following concentrations: 1,280, 640, 220, 160, 80, 40, and 20 micrograms of tobramycin per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of tobramycin that it is represented to contain. The pH of the solution containing 1,280 micrograms of tobramycin per milliliter is not less than 8.5 and not more than 10.5. The tobramycin